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**VIA CM/ECF & HAND DELIVERY**

The Honorable Leonard P. Stark  
 U.S. District Court for the District of Delaware  
 844 North King Street, Room 6325, Unit 26  
 Wilmington, DE 19801-3555

**Re: *Novartis Pharmaceuticals Corporation v. Accord Healthcare, Inc., et al.*,  
 C.A. No. 18-1043-LPS**

Dear Chief Judge Stark:

Pursuant to Paragraph 9 of the October 25, 2018 Case Scheduling Order (D.I. 216), several defendants have elected not to enter into a stipulation precluding them from launching their generic Gilenya products prior to the conclusion of this litigation. As a result, Novartis will be seeking preliminary relief with regard to those defendants (collectively, the “Participating Defendants”).

Counsel for Plaintiff and the Participating Defendants met and conferred regarding the schedule for presenting Plaintiff’s request for preliminary relief to the Court and have reached agreement on the following points, subject to approval of the Court:<sup>1, 2</sup>

Case Event	Agreed Upon Dates
Exchange Terms Requiring Construction	Feb 1, 2019
Joint Claim Construction Chart	Feb 8, 2019
Plaintiff Files PI Motion and Opening Brief	Feb. 19, 2019
Parties File Opening Claim Construction Briefs	Mar. 7, 2019
Defendants File Combined PI Answering Brief	April 9, 2019

<sup>1</sup> Plaintiff and the Participating Defendants note that the parties have agreed, subject to the approval of the Court, to move certain claim construction-related deadlines, but have retained the April 23, 2019 *Markman* hearing set by the Court.

<sup>2</sup> Mylan joins the Participating Defendants’ proposal without prejudice to the Court’s decision on Mylan’s pending motion to dismiss for improper venue in *Novartis Pharm. Corp. v. Accord Healthcare Inc.* (C.A. 18-cv-01043-LPS) (D.I. 118-120). Mylan respectfully requests the Court’s attention to Mylan’s venue challenge prior to preliminary injunction briefing.

<b>Case Event</b>	<b>Agreed Upon Dates</b>
Parties File Answering Claim Construction Briefs	April 16, 2019
Claim Construction Hearing	April 23, 2019
Plaintiff Files PI Reply Brief	May 14, 2019
Hearing on PI Motion	June __, 2019 (week of June 17 preferred)

Plaintiff and the Participating Defendants have further agreed, that given the number of parties and issues, it would be appropriate to deviate from page limits imposed by the Local Rules for the preliminary injunction briefing. Accordingly, subject to the approval of the Court, Plaintiff and the Participating Defendants jointly propose (i) that Plaintiff file a single Opening Brief of up to 30 pages in length (exclusive of declarations, exhibits, etc.) that will address the invalidity positions set forth in Defendants' invalidity contentions, including any secondary indicia that Plaintiff will be raising, (ii) that the Participating Defendants file a single Answering Brief of up to 30 pages in length (exclusive of declarations, exhibits, etc.), and (iii) that Plaintiff file a single Reply Brief of up to 15 pages in length (exclusive of declarations, exhibits, etc.).

A Proposed Order implementing these agreed upon points is enclosed herewith.

The sole issue on which Plaintiff and the Participating Defendants disagree concerns the length and format of the hearing to consider Plaintiff's motion for preliminary relief. The parties agreed to let the Court decide whether an evidentiary hearing is necessary. The parties' respective positions on this issue are set forth below.

### **PLAINTIFF'S POSITION**

Novartis respectfully submits that the need for an evidentiary hearing to resolve contested issues of fact is not yet clear. Such a hearing may not be needed or might be able to be completed in less than the two days that defendants suggest. The 405 patent has already been the subject of an extensive IPR trial proceeding in the USPTO, which found the patent to be valid under standards far less favorable to patentability than those that apply in this Court. That case involved many if not most of the same invalidity references that are mentioned in defendants' invalidity contentions in this case. The extensive IPR record plus any supplemental declarations, depositions, and documents submitted here may provide more than enough information for the Court to make an informed decision about a preliminary injunction. We thus believe that the need for an evidentiary hearing is unclear, but we defer to the Court on scheduling in view of the Court's overall docket.

### **PARTICIPATING DEFENDANTS' POSITION**

Defendants respectfully request the Court provide the parties the opportunity to present live testimony and any necessary attorney argument at the preliminary injunction hearing over the course of twelve hours. Defendants expect that the majority of the briefing and hearing will be dedicated to the issues of invalidity and irreparable harm. Allowing the parties to provide live expert testimony on these issues will permit the Court a more fulsome record on which to decide whether the various defendants should be allowed to bring to market a cost-effective generic

alternative to Novartis's Gilenya® as of the date they would be eligible for FDA approval. No 30-month stay is in place.

\* \* \*

Counsel for Plaintiffs and the Participating Defendants are available at the Court's convenience should Your Honor wish to discuss these issues.

Respectfully submitted,

/s/ Daniel M. Silver

Daniel M. Silver (#4758)

cc: Counsel of Record (via electronic mail)